

28. A method of delivering an aerosol to the lungs of a mammal comprising administering a nanoparticulate aerosol composition comprising liquid droplets having a particle size of less than about fifty microns in diameter, wherein the liquid droplets comprise:

- (a) a liquid,
- (b) crystalline particles of a therapeutic agent which is poorly soluble in said liquid, wherein the crystalline particles have an average particle size of less than about 1000 nm; and
- (c) at least one surface modifier adsorbed on the surface of the crystalline therapeutic agent particles.

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the following remarks.

I. AMENDMENTS TO THE CLAIMS

Claims 10 – 46 are pending in this application. Although Applicants traversed the restriction requirement in their response dated May 20, 2002, claims 10 – 27 and 46 nevertheless stand withdrawn from consideration. Claims 28 – 45, now under examination, are directed to a method of delivering an aerosol of a nanoparticulate therapeutic composition to the lungs of a mammal.

The amendment to claim 28 introduces no new matter. Claim 28, as amended, more particularly defines the claimed invention. Support for the amendment can be found throughout the specification at, for example, page 3, lines 14 – 20 (liquid droplets).

II. SUMMARY OF THE CLAIMED INVENTION

The claimed invention is directed to a method of delivering to the lungs of a mammal an aerosol formulation of a poorly soluble nanoparticulate therapeutic agent. Prior to the present invention, delivery of poorly soluble active agents to the lung was extremely inefficient. See specification at page 1, lines 12-14. For example, using